

REMARKS

Applicants appreciate the examination evidenced by the Office Action dated April 15, 2003. Claims 12-15, 19-21, and 23-26 are pending in the present application. Claims 12-15, 19-21, and 23-26 have been rejected. More specifically, claims 13, 15, and 23 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 12, 14, 19-21, and 24-26 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 12-15, 19-20, and 26 stand objected to by the Examiner. Moreover, claims 23-25 stand objected to by the Examiner. The concerns raised by the Examiner are addressed below as set forth in the Office Action.

I. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 13, 15, and 23 stand rejected under 35 U.S.C. § 112, first paragraph, for the reasons previously set forth in Paper No. 9, Section 5, page 2 which relies upon the reasons set forth in Paper No. 7, Section 5, pages 3-10. More specifically, Paper No. 7, Section 5, page 3 states that "the specification, while being enabling for a method of treating a solid, vascularized tumor with a chemotherapeutic agent, cisplatin, does not reasonably provide enablement for a method of treating a solid vascularized tumor with a chemotherapeutic in combination with erythropoietin."

Additionally, claims 12, 14, 19-21, and 24-26 stand rejected under 35 U.S.C. § 112, first paragraph. More specifically, the Office Action states the following:

[B]ecause the specification, while being enabling for a method of treating a solid vascularized tumor in a subject in need of such treatment comprising sequential administration of EPO followed by administration of CIS wherein said erythropoietin is administered in an amount effective to enhance suppression of endothelial growth associated with administration of said cisplatin, does not reasonably provide enablement for a method of treating a solid vascularized tumor in a subject in need of such treatment comprising administering cisplatin in conjunction with erythropoietin wherein said erythropoietin is administered in an amount effective to enhance suppression of endothelial growth associated with administration of said cisplatin, essentially for the reasons set forth previously in Paper No. 7, Section 5, pages 3-10, and Paper No. 9, Section 5, page 2) and set forth above.

Office Action, Section 6, page 4.



Applicants respectfully traverse these rejections. To further show evidence of the enablement of the claims as originally filed, Applicants submit currently herewith a Declaration under 37 C.F.R. § 1.132 of George Sigounas, Ph.D. ("the Sigounas Declaration").

The Sigounas Declaration presents results of *in vivo* studies designed to test the effects of administering erythropoietin in conjunction with cisplatin. Results from three experiments are shown at Tab 1 of the Sigounas Declaration. The data show that the weight of tumors obtained from animals injected with erythropoietin and cisplatin simultaneously was reduced by as much as 34% compared to animals injected with cisplatin alone. This difference was statistically significant ($P < 0.05$). Results of these studies indicate that administering erythropoietin in conjunction with cisplatin can reduce tumor size, and thus, can be used to treat solid vascularized tumors. Moreover, the data provided in the Sigounas Declaration coupled with the knowledge possessed by those of ordinary skill in the art and the disclosure in the present application, demonstrates enablement for methods of treating a solid vascularized tumor, comprising among other things, administering cisplatin in conjunction with erythropoietin, as recited in the claims. Thus, claims 13, 15, and 23 and claims 12, 14, 19-21, and 24-26 are enabled under 35 U.S.C. § 112, first paragraph.

Accordingly, Applicants respectfully submit that claims 13, 15, and 23 and claims 12, 14, 19-21, and 24-26 are enabled under 35 U.S.C. § 112, first paragraph, and respectfully request that this rejection be withdrawn.

II. New Grounds of Objection

Claims 12-15, 19-20, and 26 are objected to because the Office Action alleges that claim 12 recites the phrase "said antineoplastic chemotherapeutic agent" and there is no antecedent basis in the claim for this phrase. Applicants respectfully submit that claim 12, as original filed, previously recited as follows:

12. A method of treating a solid vascularized tumor in a subject in need of such treatment, comprising administering an antineoplastic chemotherapeutic agent in conjunction with an endothelial-inhibiting amount of erythropoietin.

Claim 12 was amended in the Amendment Accompanying Request for Continued Examination filed February 3, 2003. Amended claim 12 recites as follows:

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12. (Previously Amended). A method of treating a solid vascularized tumor in a subject in need of such treatment, comprising administering cisplatin in conjunction with erythropoietin, wherein said erythropoietin is administered in an amount effective to enhance suppression of endothelial growth associated with administration of said cisplatin.

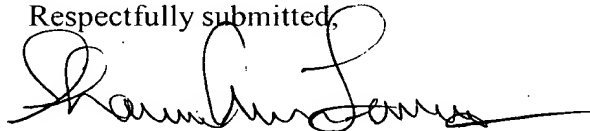
Claims 23-25 are objected to because claim 23 recites the phrase "said chemotherapeutic agent" which is noted by the Office Action as having no antecedent basis for the phrase. In the current Amendment, Applicants have amended claim 23 to recite "cisplatin" instead of "said chemotherapeutic agent."

Thus, Applicants respectfully submit that no antecedent basis issue exists with respect to claims 12-15, 19-20, 26 and claims 23-25 and respectfully request that these objections be withdrawn.

Conclusion

In view of the foregoing remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. Any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



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